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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,574	ALBANI ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,33,34,38-42 and 60-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,33,34,38-42,60-67 and 69* is/are rejected.

7)☒ Claim(s) *68 and 70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed September 23, 2004 has been received and entered. New claims 67-70 have been added, consequently, claims 1-24, 33-34, 38-42, and 60-70 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 1-19, 21, 24, 33-39, 60-62 and 64-66 under 35 U.S.C. 102(b) as being anticipated by Anderton et al is maintained.

Applicants are asserting that the claims have been amended to no longer recite a peptide comprising the amino acid sequence of SEQ ID NO: 19. Applicants further assert that Anderton does not disclose a peptide having the amino acid sequence of SEQ ID NO: 6.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Anderton et al. Applicants are respectfully directed back to their claims,

which recite an isolated HLA pan DR-binding peptide comprising a protein fragment that binds to a MHC class II molecule, wherein the fragment is up to about 30 amino acid residues in length and comprises a core sequence flanked at either end by at least one amino acid, wherein the core sequence has an amino acid sequence selected from the group consisting of SEQ ID NO: 18, 20, 21, 22 and 23.

Anderton et al (WO 95/25744) disclose of peptide fragments which are useful for protection against or treatment of an inflammatory disease, including autoimmune diseases, such as diabetes, arthritic diseases, artherosclerosis, multiple sclerosis, myasthenia gravis, or inflammatory responses due to tumor or transplant rejection. Anderton et al further disclose of the production of a fragment identical to SEQ ID NO: 21 of the instant invention. (See Table I and claims).

Consequently, the question is not whether Anderton et al teaches of SEQ ID NO: 19, but whether or not the disclosure of Anderton et al anticipates each and every limitation of the claimed invention. Given that Anderton et al disclose of a peptide with 100% identity with SEQ ID NO: 21 of the instant invention, the disclosure of Anderton et al is deemed to anticipate the instantly filed claims.

The claims are directed to an isolated HLS pan DR-binding peptide comprising a stress protein fragment that binds to a MHC class II molecule, wherein the fragment is up to about 30 amino acid residues in length and comprises a core sequence flanked at either end by at least one amino acid, wherein the core sequence has an amino acid

sequence selected from the group consisting of SEQ ID NO: 18, 20, 21, 22 and 23, and wherein the fragment comprises a naturally occurring amino acid sequence.

Anderton et al (WO 95/25744) disclose of peptide fragments which are useful for protection against or treatment of an inflammatory disease, including autoimmune diseases, such as diabetes, arthritic diseases, artherosclerosis, multiple sclerosis, myasthenia gravis, or inflammatory responses due to tumor or transplant rejection. Anderton et al further disclose of the production of a fragment identical to SEQ ID NO: 21 of the instant invention. (See Table I and claims).

In view that Anderton et al disclose of a peptide which is 100% identical to the peptide as claimed, the disclosure of Anderton et al is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The rejection of claims 1-24, 33-34, 38-42, and 60-66 under 35 U.S.C. 103(a) as being unpatentable over Anderton in view of Srivastava, Russel-Jones et al and Guichard et al is maintained.

Applicants are again asserting that the claims no longer encompass SEQ ID NO: 19 and that none of the cited references teach of an epitope as recited in the claims.

Applicants arguments have been fully addressed above in paragraph number 1, and are maintained for reasons of record.

The teachings of Anderton et al are set forth above.

Anderton et al do not teach of the peptide having one or more D-amino acids, covalently linked to an adjuvant, or of a composition comprising an interferon.

Srivastava (US Patent Number 6,455,503) teach of stress protein-peptide complexes containing a therapeutically effective amount of a cytokine including IL-1, IL-2, etc. Srivastava further sets forth that the cytotoxic T cell response may be enhanced by the presence of the cytokine. (See column 7 and claims).

Russel-Jones et al (US Patent Number 5,928,644) teach of covalent attachement of BSA to a peptide antigen results in a significant enhancement of the immune response. (See columns 2-3).

Guichard et al (Proc. Natl. Acad. Sci. USA, Vol. 91, October 1994, pp 9765-9769) teach that the use of D amino acids to replace natural L-peptides results in peptides with a higher metabolic stability, since most natural proteases cannot cleave D-amino acid residues.

Given that 1) Anderton et al have taught of fragments of stress proteins which are identical to the instantly claimed fragments (i.e., SEQ ID NO: 21), and that 2) Srivastava teaches of the desirability to incorporate cytokines with stress proteins, and

that 3) Russel-Jones teaches that covalent attachment of BSA to a peptide results in significant enhancement of the immune response, and that 4) Guichard et al has taught that incorporation of D-amino acids into a peptide results in peptides with a higher metabolic stability, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have incorporated the cytokine with the stress protein as taught by Srivastava, or to the fuse the antigen to BSA as taught by Russel-Jones et al, or to have incorporated a D-amino acid in the peptide antigen as taught by Guichard et al. One would have been motivated to incorporate these changes in view of the advantageous properties displayed by the combination (i.e., increase CTL response, increased immune response, and increased stability), as set forth by Srivastava and Russel-Jones et al and Guichard et al.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 67 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Eden et al.

The claims are drawn to an isolated peptide, wherein the amino acid sequence of the peptide consists essentially of the amino acid sequence SEQ ID NO: 6.

As set forth in MPEP 211.03 "For the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are "consisting essentially of" will be construed as equivalent to "comprising" See e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

Van Eden et al (EP 262710) disclose of polypeptide compositions and their use in therapy and diagnosis. Van Eden et al further disclose of a peptide composition which comprises a sequence with 100% identity to SEQ ID NO: 6 of the instant invention. (See abstract and page 2).

Claims 68 and 70 are objected to for depending upon a rejected base claim, however claims 68 and 70 are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
November 29, 2004